



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,444	01/09/2004	Roger A. Stern	021827-000400US	7988
21971	7590	05/24/2006	EXAMINER	
WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,444

Applicant(s)STERN ET AL. c**Examiner**

Alex B. Toy

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-27 and 34-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 29-33 is/are rejected.
- 7) ☒ Claim(s) 14 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/13/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on March 13, 2006. The 35 U.S.C. 102(b) rejections are withdrawn but the 35 U.S.C. 103(a) rejections are maintained. It is noted that in applicant's response, the Rioux reference was incorrectly identified as U.S. Pat. No. 6,954,611 B2 instead of U.S. Pat. No. 6,964,661 B2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 29-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux (U.S. Pat. No. 6,964,661 B2) in view of Wang (U.S. Pat. No. 5,462,545)

Regarding claim 1, Rioux discloses an electrode deployment apparatus for treatment of tissue in a body lumen, the apparatus comprising:

an electrode 128 arranged on a surface of a dimensionally stable support 136 (col. 5, ln. 61-63 and Figs. 1 and 3); and

The claim differs from Rioux in calling for a plurality of electrodes arranged on a surface of a dimensionally stable support at a pre-selected electrode density. Wang, however, teaches a plurality of electrodes 80 arranged on a surface of a dimensionally stable support at a pre-selected electrode density (Fig. 3D). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged a plurality of electrodes on the surface of the dimensionally stable support 136 of Rioux at a pre-selected electrode density in view of the teaching of Wang because it obvious and well-known in the art to use a plurality of electrodes on a surface used to treat tissue.

Rioux further discloses a self-expanding support to deploy and selectively expose a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density (col. 6, ln. 15-29, col. 7, ln. 43-45, and Figs. 2 and 3). The claim differs from Rioux in calling for an expansion member to expand the support instead of a self-expanding support. Rioux, however, discloses another embodiment, wherein ablation is achieved with a pair of expandable electrode arms. These arms can

Art Unit: 3739

be self-expanding (col. 9, ln. 19-28 and Figs. 13 and 14) or balloon-expanded (col. 16, ln. 5-22, col. 17, ln. 14-23, and Figs. 11 and 12). Therefore, by analogy, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the self-expanding support of Figs. 2 and 3 to have been a balloon-expanded support in view the teaching from the alternate embodiments of Rioux as an obvious alternate method of expanding the support that is known in the art.

Regarding claim 2, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Rioux discloses the apparatus further comprising wiring adapted to connect the electrodes of Rioux in view of Wang to a radiofrequency power source as a multiplicity of bipolar pairs (col. 3, ln. 3-11).

Regarding claim 3, Rioux discloses the apparatus as in claims 1 and 2 in view of Wang. In addition, Rioux discloses the apparatus, wherein the support 136 comprises a non-distensible, electrode backing (Figs. 1-3).

Regarding claim 4, Rioux discloses the apparatus as in claims 1-3 in view of Wang. In addition, Rioux discloses the apparatus, wherein at least a portion of the electrode backing is spirally furled about an expansion member prior to deployment (see the rejection of claim 1 and Fig. 3).

Regarding claim 5, Rioux discloses the apparatus as in claims 1-4 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are aligned in a generally axial direction on the surface of the electrode backing (Fig. 3D).

Regarding claim 6, Rioux discloses the apparatus as in claims 1-4 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are aligned in a generally transverse direction on the surface of the electrode backing (Fig. 3D).

Regarding claim 7, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are linear and arranged in a parallel pattern on the support (Fig. 3A).

Regarding claim 8, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are non-linear and arranged in a parallel pattern on the support (Fig. 3D).

Regarding claim 9, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes have a width in the range from 0.1 mm to 3 mm and a spacing in the range from 0.1 mm to 3 mm. Wang discloses that the electrodes are capable of any desired shape and arrangement (col. 8, ln. 15-20). Since applicant has not disclosed any criticality or unexpected result associated with these dimensions, it would require only routine skill in the art to modify the electrodes of Rioux in view of Wang to have the claimed dimensions.

Regarding claim 10, Rioux discloses the apparatus as in any one of claims 1 to 9 in view of Wang, wherein the expansion member comprises an inflatable balloon (see the rejection of claim 1).

Regarding claim 11, Rioux discloses the apparatus as in claims 1 and 10 in view of Wang, wherein the inflatable balloon inflates elastically (see the rejection of claim 1).

Regarding claim 12, Rioux discloses the apparatus as in claims 1 and 10 in view of Wang. In addition, Rioux discloses the apparatus, wherein the support is furled at least partially around the balloon, so that the support unfurls as the balloon is inflated (see the rejection of claim 1 and Figs. 2-3).

Regarding claim 13, Rioux discloses the apparatus as in claims 1, 10, and 12 in view of Wang. In addition, Rioux discloses the apparatus, wherein the support is furled in an overlapping manner (Fig. 3).

Regarding claim 29, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, the catheter of Rioux is inherently capable of use as a transesophageal catheter, and the expansion member of Rioux in view of Wang is disposed at a distal end of the catheter.

Regarding claim 30, Rioux discloses a system for treating tissue, said system comprising the apparatus as in claims 1 and 29 in view of Wang. In addition, Rioux discloses the system further comprising a RF power source coupled to the plurality of electrodes of Rioux in view of Wang (col. 3, ln. 3-11).

Regarding claim 32, Rioux discloses an apparatus as in claims 1 and 29 in view of Wang. In addition, Rioux discloses a control device 108 coupled to the plurality of electrodes, the control device providing controlled positioning of the expandable member (col. 8, ln. 24-39 and Fig. 1).

Regarding claim 33, Rioux discloses an apparatus as in claims 1, 29, and 30 in view of Wang. In addition, Rioux discloses a temperature sensor 150 coupled to the plurality of electrodes (col. 12, ln. 13-35 and Fig. 1).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux ('661) in view of Wang ('545) and further in view of Edwards ('755).

Regarding claim 31, Rioux discloses an apparatus as in claims 1, 29, and 30 in view of Wang. The claim differs from Rioux in view of Wang in calling for a multiplexer coupled to the plurality of electrodes. Edwards, however, teaches a multiplexer 25 coupled to a plurality of electrodes in order to reduce the number of electrical pathways required from the shaft lumen to the electrodes (col. 7, ln. 50-65 and Figs. 4B and 31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a multiplexer in the apparatus of Rioux in view of Wang further in view of the teaching of Edwards in order to reduce the number of electrical pathways required from the shaft lumen to the electrodes.

Response to Arguments

Applicant's arguments filed on March 13, 2006 have been fully considered and are persuasive with regards to the 35 U.S.C. 102(b) rejections of claims 1-3, 7-8, 10-11, and 29-33. Accordingly, those 102(b) rejections and the related Edwards 103(a) rejection of claim 9 are withdrawn.

Applicant's arguments with respect to the remaining 35 U.S.C. 103(a) rejections have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would be obvious to combine the teaching of Wang to use multiple electrodes on a surface used to treat tissue in on the surface 136 of Rioux as a matter of knowledge generally available to one of ordinary skill in the art.

Regarding the rejection of claim 1 using Rioux ('661) in view of Wang ('545):

Regardless of whether or not Rioux discloses multiple electrodes in the conical embodiment, it would still be obvious to one of ordinary skill in the art to place multiple electrodes on the surface 136 of Rioux in view of Wang as stated above. It is this combination that yields a support that deploys and selectively exposes a portion of the

Art Unit: 3739

electrode surface while shielding a remaining portion and maintaining the electrode density.

To summarize, Rioux discloses the expandable electrode support as claimed; it only lacks multiple electrodes. Wang teaches multiple surface electrodes, and this feature is well-known in the art. Therefore, the combination of Rioux in view of Wang yields the claimed structure that is then inherently capable of deploying and selectively exposing a portion of the electrode surface while shielding a remaining portion and maintaining the electrode density.

Allowable Subject Matter

Claims 14 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

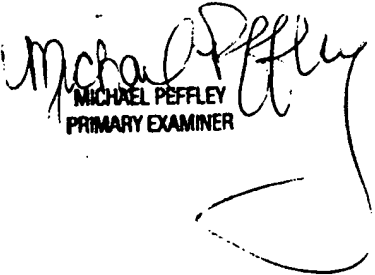
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
5/15/06


MICHAEL PEFFLEY
PRIMARY EXAMINER